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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,514	04/26/2007	Eiichi Momotani	1349.46042X00	4749
20457	7590	01/29/2009	EXAMINER	
ANTONELLI, TERRY, STOUT & KRAUS, LLP			SWARTZ, RODNEY P	
1300 NORTH SEVENTEENTH STREET			ART UNIT	PAPER NUMBER
SUITE 1800			1645	
ARLINGTON, VA 22209-3873			MAIL DATE	DELIVERY MODE
			01/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,514	<b>Applicant(s)</b> MOMOTANI ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 9 January 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 January 2009 has been entered.

Claims 1 and 3 have been amended. New claims 7-10 have been added.

2. Claims 1-10 are pending and under consideration.

#### **Rejections Withdrawn**

3. The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of the claims.

4. The rejection of claim 3 and 6 under 35 U.S.C. 112, first paragraph, scope of enablement for methods of diagnosis of any/all other mycobacterial diseases and infections using only a single antigen from any/all mycobacteria, is withdrawn in light of the amendment of the claims.

#### **Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: addition of specific antigens which would induce the claimed cell-mediated immunological reactions.

The instant claims are drawn to a diagnostic method for paratuberculosis (claims 1, 2 and 5) or any mycobacterial disease (claims 3 and 6) comprising collecting blood, adding an anti-IL10 antibody while inducing a CMI reaction against paratuberculosis or other mycobacterium, and measuring the amount of interferon-gamma present in the blood of infected versus control animals.

The missing element is the stimulus which induces said CMI reaction.

7. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a CMI mediated diagnostic method for tuberculosis, utilizing the methods of claim 3. Claim 3 recites comparing the interferon-gamma results between an infected subject and a non-infected control subject.

It is unclear what subjects are considered "non-infected" in the claimed methods considering that subjects may be vaccinated with BCG. In the case of the BCG vaccinated subjects, is the amount of interferon-gamma different than in individuals noninfected and nonvaccinated?

8. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to the method of claim 3, wherein said mycobacterial disease is leprosy and the antigen is lepromin.

Porcelli et al (U.S. Pat. No. 5,679,347, 21 October 1997) teach that cell-mediated immune response to lepromin may not occur because during a leprosy infection there is three phases, one of which results in a negative lepromin test (col. 9, lines 14-30).

Thus, it is unclear how one obtains a positive diagnosis by the instant methods in this phase of a leprosy infection.

9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to the method of claim 1 wherein the CMI induction is by addition of soluble antigen obtained "by" heat-killed *M. avium* subsp. *paratuberculosis* to said collected blood.

It is unclear what is meant by antigen obtained "by" heat-killing the bacterium.

### **Conclusion**

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 27, 2009